Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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An Assessment of Prothrombin Time Testing Practices in the Pacific Northwest

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Medical mistakes and errors are unacceptably high, despite a longstanding focus on activities carried out in the name of quality assurance, quality improvement, total quality management, and quality assessment. In 1999, a report by the Institute of Medicine (IOM) revealed the magnitude of medical errors and concluded that most were the result of systematic failures and were preventable.

One approach to reducing errors is by identifying quality indicators and developing systems for best practices. Practice standards and guidelines are developed through a consensus process that identifies specific essential requirements for materials, methods and practices. They are designed to both establish and harmonize best practices among the healthcare community.

In October 2003, the Washington State Office of Laboratory Quality Assurance (LQA) and the Centers for Disease Control and Prevention (CDC) entered into a cooperative agreement to create a model to collect and monitor laboratory quality indicators from a broad spectrum of clinical laboratories.

We selected the prothrombin time (PT) test to develop this model since it is a very common test that is vulnerable to errors and adverse patient outcomes. Patients on oral anticoagulation therapy must be monitored carefully to prevent dangerous complications of bleeding or thrombosis.

Errors can occur when an individual testing site changes to a new lot of testing reagents. Testing personnel may not recognize that their reagent sensitivity has changed and may not do studies to verify their test results are consistent and calculations are accurate.

Errors also occur when patients move from one setting to another due to a lack of correlation between methods and a lack of communication between sites. PT testing is now

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Infectious Diarrhea
- Intestinal Parasites
- Lipid Screening
- Point-of-Care Testing
- PSA
- Rash Illness
- Red Cell Transfusion
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

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commonly done in non-traditional settings and by non-traditional test methods [point-of-care (POC) and CLIA-waived test devices]. These devices differ from traditional laboratory methods by using capillary whole blood samples, unitized reagent strips or cartridges, electronic quality control devices, pre-set values for the International Sensitivity Index (ISI), mean of normal, reference range, and the automatic calculation of the International Normalized Ratio (INR). A patient may be tested while an inpatient in the hospital (by the traditional laboratory and/or at the nursing station). They may then visit an anticoagulation center as an outpatient or be tested in their physicianís office. In some cases, patients may perform PT testing at home, using one of the prescription home use devices now available. How does the patientís physician make sense of the PT values when test results come from all of these different settings, with different reference ranges, reporting formats, reagent systems, etc?

To gather information about current laboratory testing practices, a questionnaire was developed in October 2003 by the LQA and CDC, and was pilot-tested in December 2003 in five laboratories in Washington State. We researched numerous voluntary practice standards addressing PT testing that served as the basis for our questionnaire. Questions were developed to address the areas we identified to be vulnerable to errors for PT testing. These included:

- Selection of the thromboplastin reagent
- Concentration of the anticoagulant in collection tubes
- Specimen acceptance and rejection policies
- Implementation of new lots of reagents
- Contents of patient test report to clinicians

Using the Washington Medical Test Site (MTS) database and licensure application forms, testing sites performing PT by either waived or non-waived test complexity methods were identified and targeted to receive the questionnaire. Laboratories located in Alaska, Idaho and Oregon, performing proficiency testing for PT, were identified using the CLIA

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Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

Laboratory Career Recruitment

Have you been asked to give a presentation to students about careers in the clinical laboratory? The Clinical Laboratory Personnel Shortage Workgroup has developed a free PowerPoint presentation that you can use to make the job easier.

The presentation titled ì***CSI: Clinical Science Investigation***î includes information about laboratory testing, education requirements, and salary information. For more information contact Leonard Kargacin by phone at (206) 418-5416 or by e-mail at leonard.kargacin@doh.wa.gov.

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database. Questionnaires were mailed to 591 laboratories in the Pacific Northwest region in January 2004. Two hundred ninety-seven completed questionnaires were returned by March 19, 2004, resulting in an overall response rate of 50%.

Comparison of respondent demographics

	Respondents N=297	All labs targeted N=591	All Pacific NW labs N=6072
	Percent of laboratories		
Alaska	6	7	7
Idaho	15	15	12
Oregon	27	32	34
Washington	52	46	47
Urban/Rural	54/46	55/45	67/33
POL/Hospital/IL	51/39/9	56/34/10	92/5/3
Waived & PPMP/Moderate, High, Accredited	15/85	20/80	75/25

In this article, I share some of the indicators of quality and best practices for PT testing, based on recommendations found in voluntary practice standards [such as NCCLS, the World Health Organization (WHO), and the College of American Pathologists (CAP)] and current laboratory testing practices.

Because clinicians compare patient INR values against standardized therapeutic ranges and monitor trends in an individual patientís INR values over time, consistency in test values from an individual laboratory and agreement in values from different testing sites are issues of key importance.

When testing sites introduce new lots of reagents, test strips or cartridges, they should verify the ISI value in the product insert with every shipment of reagents (whether a change is expected or not). This is a simple, but effective, way to help alleviate serious calculation errors. They should establish their own patient mean of normal using the new reagent and perform parallel testing between the old and new lots. They must assure that ISI values and patient mean of normal values are correctly entered into their instrument and laboratory information systems where the INR calculation occurs. Testing personnel must alert clinicians when there is a change in values that may affect their ability to judge their patientís status.

Consistency of test results between testing sites can be improved when they use reagents with low ISI values, use specimen collection tubes with 3.2% sodium citrate, and report INRs. In addition, every site, regardless of the setting or methodology, needs to know how their INR values compare with those in another site where a patient or their sample may be referred for testing. It is common for near-patient settings to refer samples with questionable values or critical values to another site for confirmation. How do clinicians manage their patients when the two INR values do not agree?

By knowing the bias between methods, testing personnel can judge the acceptability of their own method and assist clinicians in judging the clinical significance of differences in values obtained on an individual patient tested at the two sites. In addition, both sites should communicate with each other and with clinicians whenever new methods or reagents are introduced that may change the established bias. Another correlation study may be warranted in these instances. In one published study, authors found that statistically there is a clinical equivalence of INRs that are within 0.4 at a target of 2.5 and within 0.7 at a target of 3.5.

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What *Are* Chemical Terrorism Agents, Anyway?

by Cate Franklin, PhD, DOH/PHL

Part 1 ñ Blister Agents: There are many ways to classify chemicals, such as by their chemical properties (acid, oxidizer), their physical state (solid, liquid), and their intended use (feedstock, precursor, catalyst). Chemical warfare agents (CWA), also called chemical terrorism agents, are classified by their mode of action on the exposed person: blister, blood, choking, incapacitating, nerve, tear, and vomiting agents. The table below lists some of the chemicals in each of these categories and their military designators in bold type. This is the first in a series of articles describing chemical warfare agents.

Blister	Blood	Choking	Incapacitating	Nerve	Tear	Vomiting
Mustard **H**	Hydrogen Cyanide **AC**	Phosgene **CG**	**BZ**	Sarin **GB**	**CS**	Adamsite **DM**
Lewisite **L**	Arsine **SA**			**VX**		

Selected examples of chemical warfare agents: Blister agents, also called *vesicants*, ofter are incorrectly identified as gaseous agents, i.e., ìmustard gasî rather than ìmustard.î They are, in fact, viscous liquids with boiling points beginning around 130°C and extending to greater than 250°C and are not very volatile. Blister agents include mustard (sulfur mustard), Lewisite, mustard/Lewisite mixture, the nitrogen mustards HN-1, HN-2 and HN-3, phosgene oxime, and the Lewisite-like arsenic compounds such as phenyldichloroarsine.

Blister agents have been employed as warfare agents for three reasons: to produce nonfatal casualties; to force the wearing of full protective equipment; and to clog and overwhelm medical capacity. Contact with a casualty who has not been through a decontamination procedure can lead to additional casualties. In addition, even after decontamination, a symptomatic person may still contaminate others because the damaged tissue can trap the agent, which is then released on removal or breaking of the damaged skin. Blister agents do not evaporate readily and are not generally water soluble, and can remain in soil and on surfaces for extended periods, especially if the agent was treated with a thickener.

As the name indicates, one of the usual effects of these agents is usually the formation of skin blisters at dermal contact sites with resulting tissue destruction. Some agents give an immediate nettle-like stinging followed by blister formation after several hours. Symptoms from dermal contact with other blister agents may take hours to days to appear. In humid and hot moist conditions their ability to cause skin damage increases. Exposure to blister agents initially results in eye and airway irritation, with resultant tearing, sensation of grit in the eyes, and possibly eye lesions. The severity of eye and airway irritation depends on which agent and the amount of agent present. Blister agents are cytotoxic alkylating agents that cause DNA damage similar to that caused by radiation with excessive or sustained exposure. Symptoms and severity from blister agent inhalation is also dose dependent, generally resulting in damage to mucous membranes, cough, bronchitis, and/or pulmonary edema.

There are no practical drug treatments available for preventing the effects of most blister agents. In general, the aim of treatment following exposure to a blister agent is supportive, to relieve symptoms, prevent infections, and to promote healing of the blisters. If the blistered/burned area is extensive, the patient may be admitted to a burn unit. If pulmonary symptoms are present, the patient is often treated in the ICU. Lewisite does have a drug treatment. British Anti Lewisite (BAL, dimercaprol) can be administered as an ointment for eye and skin exposure and as an intramuscular injection of a suspension of BAL in oil, but this is often reserved for patients showing severe symptoms indicating significant pulmonary injury.

Exposure to mustard blister agent can be confirmed by the detection of thiodiglycol, a breakdown product, in the exposed personís urine using GC/MS techniques. There are no clinical tests to confirm exposure to any of the other mustards. Often, however, there is sufficient material present to allow for environmental sampling and analysis to confirm the agentís identity.

For more information about the DOH Public Healthís Chemical Incident Response program contact Trace Warner (360-236-3387, trace.warner@doh.wa.gov) or Cate Franklin (206-418-5643, Catherine.franklin@doh.wa.gov). You may also contact Blaine Rhodes, Chuck Hughes, or Nathan Lacy at 206-418-5400.

Next in the series, Blood Agents

Advanced Blood Cell Morphology

Date: March 12 or March 17, 2005 **Registration Fee:** $105.00 **Course Length:** 1 day

COURSE CONTENT: This one-day course will cover the following subjects:
√ Selected cases involving WBCs, RBCs and/or platelet pathology
√ Examination of red and white cell morphology using slide presentations and quizzes
√ Microscopic examination of actual case slides
√ Lab challenges - examination of unknown specimens to test your abilities

WHO SHOULD ATTEND: This advanced course is designed for an experienced MT/MLT who would like some review and some enhancement of hematology morphology skills.

CONTINUING EDUCATION UNITS: Students will receive 0.6 CEUs for completion of this course. Applicants must attend the entire workshop to receive CEUs.

If you would like more information about this class, call Shelley Lankford, Training Program Manager, at (206) 418-5401 or e-mail the training program at PHL.training@doh.wa.gov. You can also download training registration forms at the Public Health Laboratories Training Program website at the following website: www.doh.wa.gov/EHSPHL/PHL/train.htm.

Advanced Blood Cell Morphology Training Course
Registration Form

Name:_____
Employer:_____
Employer Address:_____
City:_____ State: _____ Zip:_____
Work Phone:_____FAX:_____
E-mail:_____ Message Phone:_____

Class date (check one): _____Saturday, March 12, 2005, or
_____Thursday, March 17, 2005

HOW TO REGISTER: Complete the registration form and mail to the **Department of Health, PHL Training Program, 1610 NE 150th Street, PO Box 550501, Shoreline, WA 98155-9701** or fax to: **(206) 418-5445**. A confirmation packet will be sent to you by mail. The packet will contain your registration confirmation, payment instructions, and a map to the course location. Please **do not** send money with your registration form.

Registration Fee: $105.00 if registered on or before March 9, 2005, or $115 thereafter.

Registration deadline: Wednesday, March 9, 2005

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As part of this study, we also gathered information about general quality assurance and personnel competency assessment activities, and determined which practice standards testing sites use, and why some testing sites do not use standards to develop their policies and practices.

By sharing this report with study participants and posting it on the CDC website, we hope to raise the level of awareness of recommended standards of practice and references that may help to harmonize practices among all sites performing PT testing. Testing personnel may choose to investigate and adopt new practices based on a comparison with their peers and with recommended standards.

To review the results of the entire study, go to: http://www.phppo.cdc.gov/MLP/SurveyReports/Prothrombin_2004.aspx

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Advanced Blood Cell Morphology
March 12 Shoreline
March 17 Shoreline

Parasitology Part III: Trichrome Stains
March 23 & 24 Shoreline

2005 WSSCLS/NWSSAMT Spring Meeting
(for program details see http://www.wsscls.org)
April 21-23, 2005 Spokane

Northwest Medical Laboratory Symposium
October 26-29, 2005 Seattle

12th Annual Clinical Laboratory Conference
November 7, 2005 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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